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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/786,658 | 02/25/2004 | James B. Roane | 24310-00005 | 2856 |
| 24919 MCAFEE & T. | 7590 11/15/2007 AFT | | EXAMINER | |
| TENTH FLOOR, TWO LEADERSHIP SQUARE | | | WERNER, JONATHAN S | |
| 211 NORTH R OKLAHOMA | OBINSON CITY, OK 73102 | | . ART UNIT | PAPER NUMBER |
| | | | 3732 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| • | Application No. | Applicant(s) | | | | |
| | 10/786,658 | ROANE, JAMES B. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Jonathan Werner | 3732 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period was preply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE | J. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 30 Au | ugust 2007. | | | | | |
| 2a)⊠ This action is FINAL . 2b)☐ This | This action is FINAL . 2b) ☐ This action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) ☐ Claim(s) 1.5-7.12.16-18 and 23 is/are pending 4a) Of the above claim(s) is/are withdray 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1.5-7.12.16-18 and 23 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/o | wn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11. | epted or b) objected to by the I drawing(s) be held in abeyance. See tion is required if the drawing(s) is object. | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/30/07. | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other: | ate | | | | |

DETAILED ACTION

1. This action is in response to Applicant's amendment received 8/30/07.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 5-7, 12, and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 1 and 12, Applicant claims that the working length of each endodontic instrument is 3 mm. However, Applicant also claims that the working lengths of the second and third instruments are smaller than that of the first instrument. Such a distinction is contradictory and renders the claim indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1, 5, 7, 12, 16, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McSpadden (US 6,293,794) in view of Malmin (US 4,019,254) and

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Roane (US 4,443,193), and further in view of Hagemann et al. (US 2003/0017434). McSpadden discloses a set of progressively smaller sized instruments for performing root canal therapy (i.e. Figure 2), wherein said set as shown in the preferred embodiment of Figure 2 comprises four instruments (i.e. 20A-D), but can also include only three instruments (column 6, lines 40-43). Each instrument shown by McSpadden has an elongated shaft (i.e. 22) including a proximal end and a distal end. Also, each endodontic instrument of the set, as shown for example in Figure 2, has a relatively short, enlarged, and continuously tapered working length (i.e. 24) formed on the shaft adjacent to its distal end, wherein said working length has a diameter at its upper end that is greater than the diameter of the shaft (seen most clearly by instrument 20B), and wherein multiple cutting edges are formed by multiple flutes thereon (see Figures 3-6). Examiner points out that each subsequent instrument shown in the set of Figure 2 has a smaller working length than the instrument preceding it. McSpadden additionally discloses that the cutting edge of the instrument can run the entire length of the working length (column 2, lines 50-52), and that each endodontic instrument can further have an identical rate of taper (i.e. see Figures 7-8). McSpadden fails to disclose that the cutting edges and flutes are parallel to the axis of each instrument whereby both clockwise and counter-clockwise rotation of the instrument is thus permitted. Malmin teaches an endodontic instrument in which multiple flutes form cutting edges along the working length and wherein said cutting edges and flutes are parallel to the longitudinal axis of each instrument (i.e. Figure 7) so as to allow either clockwise or counter-clockwise rotation of the instrument while in use. Therefore it would have been obvious to one

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having ordinary skill in the art at the time of Applicant's invention to form said parallel flutes and cutting edges as described in order to permit any material that is milled off of the tooth to be aspirated out along the length of the shaft as taught by Malmin (column 4, lines 10-19). Malmin additionally shows that the cutting edges on the working length extend from the tip of said working length to its upper end (i.e. Figure 7). Still, neither Hagemann nor Malmin disclose the tip of each working length is bi-conical. Roane teaches such a bi-conical tip (78/82) on a working length of an endodontic instrument (Figure 4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to include said tip in order to guide the cutting portion of the instrument through the root canal so that lateral movement of the instrument is reduced when cutting through a curved portion of said canal as taught by Roane (see Abstract). Lastly, neither McSpadden, Malmin, nor Roane disclose a working length of each instrument to be 3 mm long. However, Hagemann et al. teach an endodontic instrument set, wherein each instrument has a working length in the range of 3 to 10 mm (paragraph 0034). Therefore, it would have been obvious to one having ordinary skill in the art to make the working length of each instrument 3 mm in order to ensure a proper fit in a patient's root canal. In regard to claims 5, 7, 16 and 18, Malmin shows each instrument can have three cutting edges on the working length formed by three flutes thereon (115, Figure 6); and the cross-sectional shape of the working length can be triangular with concave sides, triangular, square or polygonal (see Figure 6). As to claim 12, Hagemann further discloses that it is known in the art to use the set of three tools as disclosed in a "crown-down" procedure in which a tool of larger diameter is

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used first and then following with an instrument having a decreasing diameter to allow for a more extensive far reaching processing of the root canal (paragraph 0002).

Additionally, McSpadden discloses that such a crown-down procedure is capable of being performed with the instruments disclosed therein – whereby the diameter of each successive instrument is smaller than that preceding it (column 6, lines 47-59).

- 4. Claims 6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McSpadden in view of Malmin, Roane, and Hagemann et al., as applied to claims 1 and 12 above, and further in view of Buchanan (US 5,921,775). As to claims 6 and 17, Figures 15E(1-3) of Buchanan show the instrument has six cutting edges on the working length formed by three flutes thereon. Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to include such cutting edges on endodontic instruments in order to increase the number of said cutting edges to more easily and quickly cut away dead pulp from within a patient's root canal.
- 5. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over McSpadden (US 6,293,794) in view of Roane (US 4,443,193). McSpadden discloses a set of progressively smaller sized instruments for performing root canal therapy (i.e. Figure 2), wherein said set as shown in the preferred embodiment of Figure 2 comprises four instruments (i.e. 20A-D), but can also include only three instruments (column 6, lines 40-43). Each instrument shown by McSpadden has an elongated shaft (i.e. 22) including a proximal end and a distal end. Also, each endodontic instrument of

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the set, as shown for example in Figure 2, has a relatively short, enlarged, and continuously tapered working length (i.e. 24) formed on the shaft adjacent to its distal end, wherein said working length has a diameter at its upper end that is greater than the diameter of the shaft (seen most clearly by instrument 20B), and wherein multiple cutting edges are formed by multiple flutes thereon (see Figures 3-6). Examiner points out that each subsequent instrument shown in the set of Figure 2 has a smaller working length than the instrument preceding it. McSpadden additionally discloses that the cutting edge of the instrument can run the entire length of the working length (column 2, lines 50-52), and that each endodontic instrument can further have an identical rate of taper (i.e. see Figures 7-8). McSpadden, however, fails to disclose the tip of each working length is bi-conical. Roane teaches such a bi-conical tip (78/82) on a working length of an endodontic instrument (Figure 4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to include said tip in order to guide the cutting portion of the instrument through the root canal so that lateral movement of the instrument is reduced when cutting through a curved portion of said canal as taught by Roane (see Abstract).

Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan Werner whose telephone number is (571) 272-2767. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Werner

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Examiner

11/1/07

MELBA N. BUMGARNER